

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-03

☐ Other ☐ Amendment Number:Contract Number  
EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Title of Work Assignment/SF Site Name

Base Option Period Number 2

IRIS Public Science Meetings

Contractor  
ICF INCORPORATED, L.L.C.Specify Section and paragraph of Contract SOW  
A. Assessment Issues and Documents

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/01/2015 To 10/31/2016

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee:

LOE:

11/01/2013 To 10/31/2016

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Vicki Soto

Branch/Mail Code:

(Signature)

(Date)

Phone Number 703-347-0290

FAX Number:

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

(Signature)

(Date)

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

Branch/Mail Code:

(Signature)

(Date)

Phone Number:

FAX Number:

Contracting Official Name William Yates

Branch/Mail Code:

(Signature)

(Date)

Phone Number: 513-487-2055

FAX Number:

# PERFORMANCE WORK STATEMENT

Contract No. EP-C-14-001

WA 2-03

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**Title:** IRIS Public Science Meetings

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**Specify Section & Paragraph SOW:** A. Assessment Issues and Documents

**Period of PERFORMANCE:** CO award – October 31, 2016

## **I. PURPOSE**

The purpose of this work assignment is to provide administrative and logistical support to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) for up to seven IRIS public science meetings to be held during 2015 and 2016. The meetings will be held on the following schedule: December 16-17, 2015, February 2016, April 2016, June 2016, September 2016, October 2016, and December 2016, in EPA conference space located at Potomac Yard One, 2777 S. Crystal Drive, Arlington, VA 22202 or in commercial conference space arranged by the contractor. The duration of each meeting (1-2 days) will be determined approximately 1 month before the meeting when the agenda is established. The exact dates for the 2016 meetings will be determined early in 2016 based on the availability of conference space and may be revised if needed. EPA will generally release meeting materials for public review or comment before the meeting. The purpose of the meetings is to provide an opportunity for stakeholders, the public, and subject matter experts to provide input and engage with EPA in a dialogue about scientific and technical questions related to the IRIS chemical assessments and issues on the agenda.

## **II. BACKGROUND**

The EPA NCEA is part of the Office of Research and Development (ORD). EPA's Integrated Risk Information System (IRIS) program is located within NCEA. The IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health and the environment.

Public science meetings will be held approximately every 2 months. Materials for the public meetings are posted on the IRIS website (<http://www.epa.gov/iris/publicmeeting/>). The meetings provide an opportunity for the public, stakeholders, and scientific experts to provide input on preliminary materials, draft assessments or other scientific issue of importance to the IRIS program. In step 1 of the IRIS process EPA releases scoping and problem formulation materials, preliminary materials such as literature search results and preliminary evidence tables that summarize relevant studies, and key science questions to be discussed during the public

meetings. Steps 2 and 3 include Agency and Interagency review and are not involved with public science meetings. In step 4 of the IRIS process (public review and comment/independent expert peer review), EPA releases the draft assessment, draft peer review charge for public comment, and key science questions to be discussed during the public meeting. Steps 5, 6, and 7 which include completion, review and posting of the final assessment are not involved with public science meetings.

EPA welcomes all comments on step 1 and step 4 materials. In particular, EPA welcomes input on approaches for addressing key science questions, the clarity and transparency of the materials, the approach for identifying pertinent literature, the selection of studies for data extraction to preliminary evidence tables and exposure-response arrays, methodological considerations that could affect the interpretation of or confidence in study results, additional studies published or nearing publication that may provide data for assessment development. The IRIS Program believes that engagement with the broad scientific community, the public, and stakeholders can be very beneficial at the early stages of developing an assessment and at selected key points of the assessment process. Such engagement will ensure that critical research is not omitted and that key scientific issues are identified and properly frame throughout the process ultimately leading to more efficient production of assessments.

### **III. STATEMENT OF WORK**

#### **A. Objective**

The overall objective of this work assignment (WA) is to provide administrative and logistical support, and meeting facilitation, for seven IRIS public science meetings during December 2015 and October 2016. The meetings will be held in EPA conference space at the Potomac Yard One Conference Facility on 2733 S. Crystal Drive, Arlington, VA 22202. EPA has established a website to facilitate public participation. These public science meetings shall include access by webinar and teleconference lines. Stakeholders, members of the public, and scientific experts are invited to speak as opening discussants on key science questions and participate in an open dialogue on the meeting materials related to the IRIS chemicals on the Agenda. The amount of time allocated to each chemical will depend on the number of persons requesting time to participate as opening discussants and the number and complexity of key science questions. The Contractor shall provide assistance (including onsite assistance) to EPA prior to, during, and after the public meetings. Facilitation, administrative, and logistical support shall consist of the following tasks:

#### **B. Specific Requirements (Tasks)**

- 1. Establish Communication** Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.
- 2. Support Provided Before the Public Science Meetings**
  - a. In accordance with direction provided by EPA, prepare the meeting agenda and key science question documents suitable for posting to the EPA website.

- b. Manage and coordinate discussant registration and participation. Collect discussant presentation materials, respond to discussant questions, organize pre-meetings if requested by EPA, and provide guidance to discussants in accordance with EPA direction. Prepare and organize electronic files needed during the public meeting. Load all discussant and EPA presentations on the computer to be used during public meeting
- c. Prepare and electronically distribute participation guides (general and virtual) and other logistical and/or planning information to meeting registrants. Respond to questions from registrants and facilitate public and stakeholder participation.
- d. Coordinate with EPA to ensure adequate telephone and internet connections will be available at meeting location and ensure AV equipment is available and webinar room is setup before the public meeting. When requested by the WAM, provide teleconference capabilities for the meeting.
- e. If directed by the WAM, make arrangements for the use of commercial conference space including the availability of all necessary AV/IT equipment to facilitate in-person and remote participation. Remote participation will include telephone and webinar participation.
- f. Establish the registration website, monitor registration, and compile and maintain the meeting registration list. Provide updated registration lists to EPA on a weekly basis after registration opens and more frequently when registration deadlines are approaching.
- g. Provide list of attendees for EPA security no later than two work days before the meeting.
- h. Prepare name tags, name tents, meeting signs, bio-sketches (if requested), meeting agenda, and other materials routinely made available at a public meeting.
- i. Participate in up to two dry-runs prior to each public meeting including the webinar, physical room set-up, operation of all AV equipment, internet connections, and computer presentations to be used in the meetings. May include set-up of cameras, sound equipment, computer locations in room, and webinar room.

### **3. Support Provide During the Public Science Meetings**

- a. Make arrangements for and staff sign-in table during the meeting. This includes sign-in sheets, distribution of name tags and name tents, placement of meeting signs, and organization and functioning of the reception area.
- b. Provide on-site meeting facilitation to promote adherence to the schedule and a balanced opportunity for public participation from those attending within the room, via webinar, and teleconference line. Contractor will introduce opening discussants, monitor webinar and teleconference questions, read webinar questions to the meeting room, and introduce teleconference questions at appropriate times during the meeting to ensure a smooth transition between speakers and issues.



- c. Assist EPA in addressing technical difficulties raised by webinar participants, handling audio/video and webinar capabilities, and responding to participation questions from webinar participants.
- d. Establish teleconference line connection approximately 30 minutes before meetings start.

#### 4. Support After the Meetings

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. Provide attendance statistics and the results of webinar polls, if any.
- c. If directed by the WAM, provide a limited meeting summary including the general content of presentations, comments on the science questions discussed, and recommendations.

#### IV. SCHEDULE OF DELIVERABLES

	Deliverable	Due Date
1	Teleconference NTE 1 hr - outlining how all tasks (listed above) shall be performed	Within 3 days of award
2	Establish registration website	Sixty days before each meeting
3	If directed by the WAM make arrangements for commercial meeting space and all AV, webinar, and teleconference support	Sixty days before the meeting
4	Provide updates of registration status	Weekly after registration opens and more frequently when registration closure approaches
5	Coordinate discussant registration and agenda preparation	Between sixty to fourteen days before each meeting.
6.	Prepare website agenda and science questions formatted for website	Between sixty to fourteen days before each meeting.
7.	Respond to registrant questions and organize discussant coordination meetings if requested	Between sixty days before to meeting day for each meeting.
8.	Prepare and distribute meeting guides	Two to four days before each meeting
9.	Participate in meeting dry run	One to two weeks before each meeting
10.	Provide final list of in person attendees to EPA WAM/security	Two days before each meeting
11.	Staff and organize sign-in table on meeting days	Meeting days
12.	Provide name tags, name tents, and other routine meeting materials on meeting days	Meeting days
13.	Facilitate meeting – introduce discussants, maintain schedule, transition between issues, bring up presentations, coordinate webinar and teleconference questions, read webinar questions to the room	Meeting days
14	Provide final registration/attendance list and webinar attendance statistics and polling results, if any	Within five days of the conclusion of each meeting
15	If directed by the WAM provide meeting summary	Within 30 days of conclusion of meeting

## **SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at <http://www.epa.gov/oppt/greenmeetings/>.

## **VI. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

### Work Assignment Manager (WAM):

Amanda Boone-Edwards

703-347-8654

[boone-edwards.amanda@epa.gov](mailto:boone-edwards.amanda@epa.gov)

### Alternate Work Assignment Manager (AWAM)

Joe DeSantis

703-347-8616

[desantis.joe@epa.gov](mailto:desantis.joe@epa.gov)

Work Assignment Form. (WebForms v1.0)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-05				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number    1			Title of Work Assignment/SF Site Name Technical Support				
Contractor ICF INCORPORATED, L.L.C.						Specify Section and paragraph of Contract SOW A.1.(c) Human Health Assessment Documents				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2015   To   10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
11/01/2013   To   10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name   Teresa Shannon  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number   513-569-7596			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							FAX Number:			
							Branch/Mail Code:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Phone Number:			
							FAX Number:			
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:			
							Phone Number:   513-487-2852			
							FAX Number:   513-487-2107			

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-05**

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**TITLE:** Technical Support for Scientific Panel Internal Review Meetings

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**Section and Paragraph of Contract SOW:** Section A.1.(c) Human Health Assessment Documents

**PERIOD OF PERFORMANCE:** November 1, 2015 thru October 31, 2016

**I. PURPOSE**

This work assignment is a follow-on to work performed in Option Period 1 under Work Assignment # 1-05. The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Office of Research and Development (ORD), National Center for Environmental Assessment-Cincinnati (NCEA-C), in obtaining technical support services for the scientific panel internal review meetings. The Contractor shall provide professional note-taking services to support this effort.

**II. BACKGROUND**

NCEA supports the Superfund Program by developing provisional toxicity values (PTVs) such as reference doses, reference concentrations, and cancer values for chemicals where such information is not available in EPA's Integrated Risk Information System (IRIS). Provisional toxicity values are documented in Provisional Toxicity Value documents.

In order to streamline the PTV review process and ensure consistency, an internal scientific review panel was established by NCEA-C to review each chemical and resolve technical issues prior to the completion of an external peer review and the clearance process. The scientific internal review panel meets on a regular basis (once per month or as deemed necessary) for approximately 3 hours per meeting. The Panel consists of seven technical reviewers (EPA senior scientists) and one professional note-taker.

**III. STATEMENT OF WORK**

**Task 1: Establish Communication** - Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the EPA WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

**Task 2: Work Plan and Staffing Plan** - The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, showing assigned personnel by task and the qualifications of the proposed personnel.

**Qualifications** - The Contractor shall provide a qualified professional note-taker with a minimum of 8 years of experience in risk assessment, toxicological terminology, and related topics.

**Specific Requirements** - The Contractor is requested to begin work under this WA immediately upon receipt from the Contracting Officer, while simultaneously preparing a Work Plan.

**Task 3: Preparation for Panel Meeting** - The Contractor shall provide professional note-taker services to perform Tasks 3 – 6, for up to 10 Panel Meetings to be held during the period of performance of this WA. The professional note-taker services shall include preparing for each scientific review panel meeting by completing an overview of the designated PTV draft manuscripts and checklists to be reviewed during each meeting. During each Panel Meeting, a total of 1-3 chemicals will be discussed. Written information for each chemical typically ranges from 30-75 pages in length. Access to information for each chemical will be provided to the Contractor a minimum of five (5) business days in advance of each scheduled meeting by the EPA WAM. The Contractor shall obtain the required information through SharePoint and/or the Health and Environmental Research Online (HERO) database.

**Task 4: Schedule for Panel Meetings** - The Contractor shall provide note-taker services via teleconference. All meetings will take place at the U.S. Environmental Protection Agency, Andrew W. Breidenbach Environmental Research Center, 26 W. Martin Luther King Drive, Cincinnati, OH, 45268. The meetings typically are held in the afternoon between noon and 5:00 pm. The meeting dates and times will be set by the EPA WAM at least 1 week in advance. The first Panel Meeting for this Performance Period will be determined by the EPA WAM. The Contractor will be notified by the EPA WAM of all scheduled meetings via written technical direction.

**Task 5: Draft Written Reports** - The Contractor shall provide a draft written report of the results of each scientific review panel meeting to the EPA WAM within 4 business days following the meeting. In response to the draft written report, the EPA WAM will provide any comments, changes, or questions to the Contractor within 5 business days after receipt.

**Task 6: Final Written Reports** - Upon receipt of the EPA's response, the Contractor shall provide a final written report of the results of each scientific review panel meeting to the EPA WAM within 5 business days.

#### **IV. ANTICIPATED DELIVERABLES**

All written deliverables shall be provided in electronic format in Microsoft Word.



## **V. DELIVERABLES AND SCHEDULE**

Task 1 – Establish Communication	Within 3 days of start of WA
Task 2 – Work Plan and Staffing Plan	Begin work immediately and simultaneously prepare Work Plan and Staffing Plan within 15 calendar days after receipt of WA
Task 3 – Preparation	Prepare for scientific review panel meetings within 5 days of each meeting
Task 4 – Panel Meetings	Furnish professional note-taker to attend up to 10 Panel Meetings, as scheduled by the EPA WAM
Task 5 – Draft Written Report	After each Panel Meeting, provide a draft written report to the EPA WAM within 4 business days
Task 6 – Final Written Report	Upon receipt of WAM's response to each draft written report, provide a final written report to the EPA WAM within 5 business days

All deliverables shall be submitted electronically as Microsoft Word documents. Electronic (pdf) copies of all deliverables shall be sent to the EPA Project Officer (PO) shown below.

## **VI. MANAGEMENT CONTROLS**

1. The Contractor shall certify there is no conflict of interest. The Contractor shall provide the following conflict of interest certification in the Work Plan:

I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this WA exist. Personnel who perform work under this WA, or relating to the WA, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this WA have been reported to the EPA WAM or are attached, if applicable.

2. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
3. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
4. The Contractor shall comply with other applicable requirements for final WA reports stipulated in the Agreement.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (a) Formulation of Agency policy
- (b) Selection of Agency priorities
- (c) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or Work Assignment, the contractor shall immediately contact the EPA WAM.

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The Contractor shall hold a conference call with the EPA WAM at the initiation of the WA, and shall provide a bi-weekly update to the EPA WAM by telephone as necessary, or in the form of a report submitted via email, for the duration of the WA. The Contractor shall be prepared to participate in additional conference calls or email exchanges, as necessary.

## **IX. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

### **Work Assignment Manager (WAM)**

Teresa Shannon  
513-569-7596  
513-487-2542 (fax)  
[shannon.teresa@epa.gov](mailto:shannon.teresa@epa.gov)

### **Alternate Work Assignment Manager (Alt. WAM)**

Scott Wesselkamper  
513-569-7256  
513-487-2539 (fax)  
Email: [wesselkamper.scott@epa.gov](mailto:wesselkamper.scott@epa.gov)

Mailing Address:  
U.S. Environmental Protection Agency  
National Center for Environmental Assessment  
26 W. Martin Luther King Drive  
MS-A110  
Cincinnati, OH 45268

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-05



Other



Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base Option Period Number 2

Title of Work Assignment/SF Site Name

Technical Support for Scientific

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Section A.1.(c) Human Health Assessment Documents

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/01/2015 To 10/31/2016

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
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## Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee: \$0.00

LOE: 0

11/01/2013 To 10/31/2016

This Action:

\$30,312.00

235

Total:

\$30,312.00

235

## Work Plan / Cost Estimate Approvals

Contractor WP Dated: 11/20/2015

Cost/Fee: \$30,312.00

LOE: 235

Cumulative Approved:

Cost/Fee: \$30,312.00

LOE: 235

Work Assignment Manager Name Teresa Shannon

Branch/Mail Code:

(Signature)

(Date)

Phone Number 513-569-7596

FAX Number:

Project Officer Name Melissa Revely-Wilson

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**Work Assignment Number  
2-05☐ Other ☒ Amendment Number:  
000001Contract Number  
EP-C-14-001Contract Period 11/01/2013 To 10/31/2016  
Base Option Period Number 2Title of Work Assignment/SF Site Name  
Technical SupportContractor  
ICF INCORPORATED, L.L.C.Specify Section and paragraph of Contract SOW  
A.1.(c) Human Health Assessment DocumentsPurpose: ☐ Work Assignment  
☒ Work Assignment Amendment  
☐ Work Plan Approval☐ Work Assignment Close-Out  
☐ Incremental FundingPeriod of Performance  
From 11/01/2015 To 10/31/2016

## Comments:

This amendment is to remove the NOTE TAKER from the PWS as it is no longer needed and to reduce the hours by 173 and total cost \$14,634.74. All other terms and conditions remain unchanged.

☐ Superfund

## Accounting and Appropriations Data

☒ Non-SuperfundSFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
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## Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 Cost/Fee: LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee LOE:

Cumulative Approved: Cost/Fee LOE:

Work Assignment Manager Name Teresa Shannon

Branch/Mail Code:

Phone Number: 513-569-7596

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <h1 style="margin: 0;">EPA</h1> </div> <div> <p>United States Environmental Protection Agency Washington, DC 20460</p> <h2 style="margin: 0;">Work Assignment</h2> </div> </div>		<p>Work Assignment Number 2-07</p> <p><input type="checkbox"/> Other    <input type="checkbox"/> Amendment Number:</p>								
Contract Number EP-C-14-001	Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number           1	Title of Work Assignment/SF Site Name Dose-Response and Quantitative								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW A.1   and   B.1,2,5								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From   11/06/2015   To   10/31/2016								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
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Contract Period: 11/01/2013   To   10/31/2016		Cost/Fee:				LOE:				
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name   John Fox  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number   703-347-8598			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:   703-347-8523			
							FAX Number:   703-347-8696			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:   513-487-2852			
							FAX Number:   513-487-2107			

**PERFORMANCE WORK STATEMENT  
CONTRACT NO. EP-C-14-001  
WA 2-07**

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**TITLE: Dose-Response and Quantitative Analysis Support**

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**Principal Section & Paragraph of SOW: A.1 and B.1,2,5**

**PERIOD OF PERFORMANCE: CO Issuance – October 31, 2016**

## **I. PURPOSE**

This work assignment is a follow-on to work performed under Work Assignment # 1-07. The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of Dose-Response and Quantitative Analyses in Support of IRIS. More specifically, this work assignment will continue to provide dose-response analyses, statistical analyses, and other quantitative analyses and research as identified in the contract performance work statement, Sections A(1) and B(1,2, and 5). Data entry and data QA, and data management will be a part of these tasks. Reporting of results in tables of standard IRIS formats will be a part of these tasks.

## **II. BACKGROUND**

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.



### III. SCOPE OF WORK: TASKS AND DELIVERABLES

#### Requirements Specific to this PWS

The contractor shall provide personnel who are proficient with the software tools DRAGON, WIZARD, Microsoft Access, Microsoft Excel, and knowledgeable regarding dosimetric conversions. BMDS (Benchmark Dose Software (<http://www.epa.gov/ncea/bmds>)) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (\*.d), \*.dax, \*.ssn, \*.opt).

Under this PWS, an episode of work (aka “request”) will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (enumerated below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager.

Agency guidance will be applied and exceptions to such guidance will be clearly noted. Agency guidance should be used: (a) to determine the suitability of studies and data used; (b) to guide the preparation of data and the adjustment of doses or concentrations for intermittent and time-varying exposures and less-than-lifetime exposures; (c) to guide the conduct of dose-response modeling and model selection; (d) to guide the development of RfC/RfD values, cancer slope factors, and all other subject matter included in Chapters 5 and 6 of a Toxicological Review.

The work shall be conducted so as to be consistent with EPA’s *Benchmark Dose Technical Guidance Document* and other relevant EPA guidelines (e.g., guidelines for carcinogen risk assessment, neurotoxicity, reproductive toxicity, developmental toxicity, and inhalation dosimetry (see documents at <http://www.epa.gov/iris/backgrd.html>)). Quantitative dose-response analyses shall be conducted and reported according to the *Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS*, to be provided by EPA. If any exceptions to the foregoing guidance and checklist are required for an analysis, they should be noted and explained.

Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files (\*.d), \*.out, \*.opt, \*.ssn]). The contractor shall use the most recent issue of BMDS (BMDS 2.x) for dose-response analyses, where this is feasible and efficient; otherwise, the contractor shall use the latest versions of BMDS executable ‘modules’ (e.g., multistage.exe) if the latest GUI is not used [these modules are installed with BMDS 2.x].

Input data and BMDS accessory files developed under this Task for the various dose-response analyses shall be delivered. This includes spreadsheets, input files to the BMDS Wizard, and accessory files used and produced by BMDS (e.g., BMDS related files: \*.d), \*.set, \*.dax, \*.opt, \*.ssn, \*.out, \*.002, \*.plt, \*.emf, and Excel export files from BMDS2). These materials will be organized in subdirectories or by file names so as to distinguish cancer and noncancer effects, exposure routes (inhalation, diet, drinking water), and continuous vs. dichotomous (quantal) responses. These files shall be named or described (e.g. in a Read\_Me.txt file or other document) or otherwise organized sufficiently that the data sets and endpoints are recognizable. These materials will be transmitted in electronic form, e.g., by email in a ZIP file or delivered physically on a CDROM.

The contractor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contractor will provide access to this internal documentation upon request by the EPA WAM (Work Assignment Manager) or EPA Project Officer.

### **Task 1: Quality Assurance Project Plan (QAPP) and Work Plan**

The contractor shall develop both a Work Plan and a quality assurance project plan (QAPP) for this project. These shall state that the QAPP will be observed during the conduct of this work assignment. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP and Work Plan

Due Date: 15 days after issuance of this Performance Work Statement (PWS).

### **Task 2. Data Entry and Data QA**

The contractor shall review data sources to identify data for each endpoint, enter the data into an electronic medium (if not already provided in this form), and verify the data. All data shall be verified as correctly entered from the source. Source publications will usually be accessed using EPA's HERO database.

The contractor is not responsible for verifying secondary data quality for studies and endpoints identified by the EPA WAM unless required to do so in the written Technical Direction pertaining to a specific request.

The contractor will provide, to the EPA WAM, spreadsheets that indicate the source of the individual data element from a study by reference to the page, table, figure, footnote, etc., from the original report being cited. Data will be entered in the units provided in the original paper, with any necessary transformations explicitly performed in the spreadsheet. Units conversions and adjustments for intermittent or non-constant exposure shall be documented explicitly for each data set, with comments as needed. Possible cases of systematic differences in survival between dose groups (typically, lower survival in high dose groups) will be 'flagged'.

When a request involves multiple studies, data will be assembled and organized in either the BMDS WIZARD or in DRAGON, unless the contractor and the EPA WAM agree not to do so.

Deliverables: Notification of completion to EPA WAM by email or telephone. As necessary, questions and problems regarding data will be delivered, with proposed methods of resolution.  
Data will be delivered after task 2 completion only if specifically requested (usually the data will be delivered with results of benchmark dose analyses under the Tasks that follow this one).

Due Dates: To be specified either in written technical direction after consultation with the contractor, or, if not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.

### **Task 3: Non-Cancer Data Analysis and Benchmark Dose Modeling**

Under this task, the contractor will evaluate non-cancer data sets for dose-response modeling in a manner consistent with EPA's Benchmark Dose Technical Guidance Document and Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS. The contractor will consult with the EPA WAM as to potential problems with particular experiments and data sets. Prior to modeling data, the contractor will perform any necessary dosimetric adjustments and/or conversions, select appropriate benchmark responses (BMRs) for each endpoint, identify important or unusual statistical issues, and flag data not amenable to benchmark dose modeling. Additionally, the contractor will perform data verification and documentation as outlined in Task 2 prior to dose-response modeling.

To facilitate comparison of multiple candidate PODs, summary results for BMDs, BMDLs, NOAELs and LOAELs will be reported in terms of Human-Equivalent Dose or Concentration (HED/HEC). For chronic and subchronic oral (ingestion) exposures (specifically excluding developmental and short-term studies), a BW<sup>3/4</sup> default animal-human conversion be made. Reporting units will be mg/kg-day for oral exposure and either ppm or mg/m<sup>3</sup> for inhalation exposure. RfDs will be reported in mg/kg-day and RfCs will be reported in mg/m<sup>3</sup>.

The contractor will model data amenable to benchmark dose modeling using EPA's BMDS2.x. Results will be summarized in tables that report key statistics for model goodness of fit (AIC, p-value for goodness of fit, degrees of freedom for the Chi-square test, and largest scaled Chi-square residual). Based on these results along with considerations of biological relevance, the contractor will identify candidate data sets, endpoints, and models that could be used as a basis for a POD for both ingestion and inhalation exposure routes, as the data permit. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route  
Due Date: 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data  
Revisions – dates to be specified in written technical direction

### **Task 4: Cancer data analysis and dose-response modeling**

Under this task, the contractor will review the study reports identified by the EPA WAM to identify data sets on cancer incidence amenable to analysis of individual tumor sites. For both ingestion and inhalation exposure routes, as the data permit, cancer data amenable to benchmark dose modeling will be prepared and verified as outlined in Task 2.

The contractor will also identify studies amenable to modeling risk from multiple tumors per animal (when data exists for multiple tumor sites in one study for one sex of one rodent strain, EPA may request an analysis of risk from multiple tumors using the MS\_COMBO program or using the "multi-tumor" option of BMDS).

Individual tumor data will be fitted using the 'multistage cancer model' of BMDS (with coefficients constrained to be non-negative). Multistage model order selection will be based upon a minimum AIC criterion unless otherwise specified in writing.

After conducting BMDS modeling, the contractor will identify those data sets, endpoints, and models (i.e., orders of the multistage model) that could be used as a basis for unit risk/cancer slope factor. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

**Deliverable:** spreadsheets holding input data; output (analysis) results by data set with recommended models; summary tables showing key results for selected models for the various datasets (endpoints) by exposure route

**Due Date:** 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data

Revisions – dates to be specified in written technical direction

### **Task 5: Time to Tumor Analysis**

The contractor may be requested to review cancer bioassay studies (provided by the EPA WAM) to identify and propose those for which time to tumor analysis may need to be applied, or such studies may be identified by the EPA WAM. Time-to-tumor analysis would need to be applied if survival differs substantially among the dose groups.

The contractor will use the "MSW" program for time-to-tumor analysis and will report any failures of the MSW program to solve the BMDL. If this occurs, the program "ToxRisk" (version 5.3) will be used to obtain a BMDL. Subsequently, parameter estimates and BMD resulting from MSW and ToxRisk will be compared to determine similarity. The contractor will also call attention to any instances of parameter estimates on a boundary. Where higher-order coefficients are nonzero, estimates will be presented for all model orders between 1 and the number of dose groups less 1. The EPA WAM may request a conventional BMDS cancer-model analysis based on poly-3 weights applied to the individual animal data, as an alternative to time-to-tumor modeling.

**Deliverables:** input and output files used/produced by software to fulfill this task (text files and/or spreadsheets); a report with tables summarizing the data, data sources, and results, suitable for inclusion in an Appendix to a Toxicological Review

**Due Date:** to be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor

### **Task 6: Prepare Draft Materials for IRIS Toxicological Reviews**

The contractor, when requested in a technical directive, shall prepare draft portions of an IRIS Toxicological Review, relevant to dose-response or quantitative analyses conducted under other tasks herein, and following the style of the IRIS template for Toxicological Reviews (to be provided by EPA). Drafts may include Evidence Tables, Study Summaries, exposure-response arrays, dose-response modeling, selection of an oral reference dose (RfD), inhalation reference concentration (RfC), cancer modeling (including derivation of a cancer slope factor and inhalation unit risk), Chapter 2 text and tables, Appendix materials, and related narratives. EPA may also request various types of graphical displays of data.

**Deliverables and Due Dates:**

Drafts with supporting materials, date to specified in written technical direction.  
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.  
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

## **Task 7. Study and Endpoint Screening and Selection for Hazard ID and Dose-Response Analysis**

This task may require:

- review of studies for adequacy to support inferences about toxicity and carcinogenicity, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- review of studies to support dose-response analysis, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- preparation of “evidence tables” in the current IRIS format or new formats
- other tabulations of studies using a layout provided by EPA or proposed by the contractor and confirmed by EPA, and computations needed to calculate results for such tabulations
- graphical presentations comparing studies and endpoints quantitatively and qualitatively, including but not limited to exposure-response arrays and forest plots, and including computations needed to calculate results for such plots
- graphical displays of data, statistics, estimates and endpoints

If so requested, the contractor will document in such tables the preliminary decisions (including rationales) about critical endpoints, to include (of so directed) MOA, sensitive populations, and candidate/principal studies for hazard evaluation and RfV derivation.

If so requested, the contractor will document the details that support preliminary decisions regarding potential critical endpoints, MOA, sensitive populations, and candidate/principal studies.

The EPA WAM will communicate detailed requirements by Technical Directions when this Task is undertaken, and will provide examples from recent Assessment documents.

Deliverables: Spreadsheet worksheets and Word tables; supporting narrative and appendices when requested  
Due Dates:

Drafts with supporting materials, date to specified in written technical direction.  
Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.  
Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

## V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

<b>Task</b>	<b>Schedule</b> (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this PWS
2. Data Entry and QA	To be specified in written technical direction. If not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.
3. Non-Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
4. Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
5. Time-to-Tumor Modeling	To be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor
6. Draft Materials for IRIS Tox. Reviews	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA
7. Study and Endpoint Screening	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA



## **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

## **VII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

## **VIII. EPA CONTACTS**

### EPA Work Assignment Manager (WAM)

John Fox

703-347- 8598 (voice), 703-347-8690 (fax), email [Fox.John@epa.gov](mailto:Fox.John@epa.gov)

Mailing Address:

U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)

1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:

U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment

Two Potomac Yard North, 7<sup>th</sup> Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

### EPA Alternate Work Assignment Manager (Alt-WAM)

Christine Cai, 703-347- 8517 (voice), 703-347-8689 (fax), email [cai.christine@epa.gov](mailto:cai.christine@epa.gov)

(same as for WAM)

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-07

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base Option Period Number 2

Title of Work Assignment/SF Site Name

SWG support for IRIS

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

A.1 and B.1,2,5

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/06/2015 To 10/31/2016

Comments:

The WAM recommends conditional approval, with initial funding not to exceed the \$23,288 and 276 hours. At this time we do not anticipate requiring more than 276 hours



Superfund

## Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 Cost/Fee: \$0.00 LOE: 0

This Action: \$23,288.00 276

Total: \$23,288.00 276

## Work Plan / Cost Estimate Approvals

Contractor WP Dated: 11/30/2015 Cost/Fee: \$23,288.00 LOE: 276

Cumulative Approved: Cost/Fee: \$23,288.00 LOE: 276

Work Assignment Manager Name John Fox

(Signature)

(Date)

Branch/Mail Code:

Phone Number 703-347-8598

FAX Number:

Project Officer Name Melissa Revely-Wilson

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-08				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number       2			Title of Work Assignment/SF Site Name Software Tools				
Contractor ICF INCORPORATED, L.L.C.						Specify Section and paragraph of Contract SOW C. Risk Assessment Data Bases and Computer Tools				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/06/2015   To   10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 11/01/2013   To   10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee:                      LOE:										
Cumulative Approved:                      Cost/Fee:                      LOE:										
Work Assignment Manager Name   John Fox  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number   703-347-8598			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:   703-347-8523			
							FAX Number:   703-347-8696			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code:			
							Phone Number:   513-487-2852			
							FAX Number:   513-487-2107			

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-08**

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**TITLE: Software Tools to Support IRIS Data Management, Analysis and Reporting**

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**Principal Section & Paragraph of SOW: C. Risk Assessment Data Bases and Computer Tools**

**PERIOD OF PERFORMANCE: CO Issuance - October 31, 2016**

## **I. PURPOSE**

This work assignment is a follow-on to work performed under Work Assignment # 1-08. The purpose of this Performance Work Statement (PWS) is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of "Software Tools to Support IRIS Data Management, Analysis and Reporting." More specifically, this work assignment will continue to provide software tools and templates to support data management and quality assurance, summarization and analysis of data (e.g., for hazard evaluation and dose-response modeling) and the organization and reporting of these data and analyses, primarily for the preparation of toxicological reviews by NCEA's IRIS program.

## **II. BACKGROUND**

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.

### **III. SCOPE OF WORK: TASKS AND DELIVERABLES**

#### **Requirements Specific to this PWS**

This PWS supports continued development and modification of software tools (DRAGON, WIZARD, and the dosimetry tool, and exposure-response array) that are based on Microsoft Access, Microsoft Excel, and associated Visual Basic for Applications code. Therefore, the contractor shall provide personnel who are already expert in the areas of (a) QA and revision control for program codes, (b) Visual Basic for Applications programming, (c) applications based on commercial spreadsheets (specifically, Microsoft Excel) and (d) commercial database management systems (specifically, Microsoft Access). This shall not rule out the use of other platforms and software utilities.

BMDS (Benchmark Dose Software; at <http://www.epa.gov/ncea/bmds>) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (\*.d), \*.dax, \*.ssn, \*.opt).

#### **Task 1: Quality Assurance Project Plan (QAPP) and Work Plan**

The contractor shall develop both a Work Plan and a quality assurance project plan (QAPP) for this project. These shall state that the QAPP will be observed during the conduct of this work assignment. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP and Work Plan

Due Date: 15 days after issuance of this Performance Work Statement (PWS).

#### **Task 2. MS/Word templates**

Background: "Streamlining" (revising the content and format) of IRIS toxicological reviews is an ongoing process which will be informed by feedback from the National Academy of Sciences, reviewers, and stakeholders. From time to time, EPA may require new or revised MS-Word templates (associated with BMDS Wizard and Dragon) as IRIS revises its formatting of toxicological reviews. EPA may also require changes or additions to the data-management, calculation and reporting capabilities of Wizard and Dragon to support changes in data calculations and changes in reporting for toxicological reviews.

The contractor will create or revise (as appropriate) MS/Word templates and styles used to create tables for use in IRIS toxicological reviews. These include (but are not limited to) Study Summary tables, tables summarizing modeling results, and Evidence Tables.

EPA expects modifications to MS/Word templates associated with epiDRAGON, reflecting the anticipated modifications and additions to the software as described in Task 3. The contractor will create or revise (as appropriate) MS/Word templates and styles used to create tables for use in IRIS toxicological reviews. These include (but are not limited to) Study Summary tables, tables summarizing modeling results, and Evidence Tables.

EPA expects to request one revision to each template currently in use, and development of two new templates.

Deliverables: revised MS-Word templates

Due Dates: to be specified in written technical direction

### **Task 3. DRAGON (Dose Response Analytical Generator and Organizational Network)**

EPA expects to request additions of new data fields and simple calculations in Dragon, to support reporting needs for evidence tables. For the purpose of costing this PWS, the contractor should assume that a dozen such changes may be requested by EPA. Changes or additions to data fields for developmental studies can be expected. Data forms or fields for neuro-developmental or neuro-toxicological studies will be added.

This Task covers additions to and modifications of various "modules" in DRAGON and their integration into a single databases system. Modules include but are not limited to "epiDRAGON", "cellDRAGON", "animalDRAGON", and "Management module".

Export and import capabilities (e.g. for data exchange with Meta-data Viewer, Graphpad, and Excel) may be requested. Forms, or export capabilities, or reporting formats compatible with HERO may be requested.

The contractor will verify correct operation of DRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use.

This work assignment will continue and extend development of DRAGON but shall not duplicate work already done for the federal government. [For example, modifications to DRAGON made under another work assignment would not be repeated under this work assignment.]

EPA expects to continue to request additions of data fields and capabilities in "epiDRAGON," to support reporting needs for study methods tables, evidence tables, exposure-response arrays, and dose-response analysis. This may include specialized fields for different study designs, exposure scenarios, and outcome types (e.g., cancer, neurodevelopmental, etc.). Modifications to epiDRAGON are expected to be iterative, with periodic evaluation performed using 'test' or 'practice' sets of data/studies. The contractor will verify correct operation of epiDRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use. This work assignment will continue and extend development of epiDRAGON but shall not duplicate work already done for the federal government. [For example, modifications to epiDRAGON made under another work assignment would not be repeated under this work assignment.]

#### Deliverables and due dates:

- New and revised fields and forms will be specified in written technical direction
- Drafts of DRAGON for review - arranged by consultation with WAM
- Reports on testing with 'practice data' – approx. every 4 weeks during development
- Wizard modeling templates – to be requested in written technical directions
- Word report/table templates – to be requested in written technical directions

### **Task 4. User Manuals, Tutorials, and Presentations**

User manuals will be developed for DRAGON and WIZARD (these will also cover use of the imbedded dosimetry tool). Scope: the manuals will provide users with instructions for use, but are not expected to explain the workings of Access or Excel or the details of the associated VBA code. Manuals will be provided with databases that may be used in the manuals as examples and can be used by users as templates. Necessary information will be provided separately on any modifications (including VBA code) and configuration steps needed to use these databases on a proxy server.



Tutorials or presentations of DRAGON capabilities will be provided (dates to be determined in consultation with EPA). These may take the form of demonstration/lectures, either on-site at EPA locations or as webinars. Provision will be made for user questions and answers. EPA expects to request two demonstration/lectures or basic tutorials, one at each of two EPA locations.

Deliverables and due dates:

Manuals: draft within 15 working days of receipt of technical direction to begin this task; revised drafts within 10 working days after EPA returns comments

Tutorials and Presentations: dates to be arranged in consultation with EPA

## **Task 5. Graphical Display Methods**

A variety of graphical display methods are required for animal toxicology data and epidemiological data. These may be implemented using commercial software or custom program code, either separate from DRAGON or integrated with DRAGON, depending on efficiencies and ease of use. EPA may request examples of alternative methods of graphic display before deciding on one or more methods. Graphic display methods will be user-tested by providing graphics for several IRIS assessments, involving 10-120 estimates or endpoints and 4-24 graphics per assessment.

Deadlines: draft within 15 working days of receipt of technical direction to begin this task; revised drafts within 10 working days after EPA returns comments

## **Task 6. BMDS WIZARD**

The BMDS WIZARD will be updated to accommodate changes to BMDS as these occur and if BMDS changes require modifications to the WIZARD. The contractor should notify the WAM when a need is determined; work will then be initiated after receipt of written technical direction from EPA. Other changes to WIZARD (e.g., the Logic page) may be requested by the EPA WAM. Based on recent experience, EPA expects there will be one update to BMDS, and 5-6 smaller requests for minor modifications to WIZARD.

Deliverables: revised BMDS WIZARD

Deadlines: to be specified in written technical direction

## V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

<b>Task</b>	<b>Schedule</b> (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan and Work Plan	15 days* after receipt of this PWS
2. MS/Word templates	to be specified in written technical direction
3. DRAGON	Drafts of DRAGON for review: arranged by consultation with WAM Developmental forms: mid-December 2013
	Oral reports on testing with practice data or in use for EPA projects – approx. every 4 weeks during development
	Beta versions of DRAGON after adding new modules - arranged by consultation with WAM
	Revisions in response to EPA comments - 14 work days after receiving technical direction
4. User Manuals and Tutorials	Manuals: draft within 20 working days of approval of this task. Revised drafts within 10 working days after EPA returns comments. Tutorials: dates to be arranged in consultation with EPA
5. Graphical Display Methods	to be determined in consultation with EPA and other users
6. BMDS WIZARD	to be specified in written technical direction

## **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

## **VII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

## **VIII. EPA CONTACTS**

### EPA Work Assignment Manager (WAM)

John Fox

703-347- 8598 (voice), 703-347-8690 (fax), email [Fox.John@epa.gov](mailto:Fox.John@epa.gov)

Mailing Address:

U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)

1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:

U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment

Two Potomac Yard North, 7<sup>th</sup> Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

### EPA Alternate Work Assignment Manager (Alt-WAM)

Glinda Cooper, 703-347-8636 (voice), email [Cooper.Glinda@epa.gov](mailto:Cooper.Glinda@epa.gov)

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-08

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base Option Period Number 2

Title of Work Assignment/SF Site Name

Software Tools

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

C. Risk Assessment Data Bases and Computer Tools

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/06/2015 To 10/31/2016

Comments:



Superfund

## Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee: \$0.00

LOE: 0

11/01/2013 To 10/31/2016

This Action:

\$28,543.00

340

Total:

\$28,545.00

340

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

11/30/2015

Cost/Fee: \$28,543.00

LOE: 340

Cumulative Approved:

Cost/Fee: \$28,545.00

LOE: 340

Work Assignment Manager Name John Fox

(Signature)

(Date)

Branch/Mail Code:

Phone Number 703-347-8598

FAX Number:

Project Officer Name Melissa Revely-Wilson

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-10				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number      2			Title of Work Assignment/SF Site Name Pb Rulemaking				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW D. Analysis, Document & Issue Paper Preparation, E					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2015   To   10/31/2016				
Comments: D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
11/01/2013   To   10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name   Charles Bevington							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number   202-564-8814			
							FAX Number:			
Project Officer Name   Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:   703-347-8523			
							FAX Number:   703-347-8696			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name   Adam Meier							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:   513-487-2852			
							FAX Number:   513-487-2107			

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-10**

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**TITLE:** Preparing Materials on Public and Commercial Buildings (P&CBs) for Pb Rulemaking

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**Specify Section & Paragraph SOW: Please select from the following:** D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

**PERIOD OF PERFORMANCE:** 11/01/2015 to 10/31/16

**I. PURPOSE**

The purpose of work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT), in the completion of the Estimation of Health Effects from Exposure Scenarios that disturb Lead Based Paint from Exteriors and Interiors of Public and Commercial Buildings.

**II. BACKGROUND**

EPA is undertaking rulemakings intended to revise certain provisions of the Lead Renovation Repair and Painting (LRRP) Rule and to cover public and commercial buildings not covered by the LRRP rule. Under previous work assignments, the contractor provided support for many activities including the following:

- Developing an approach for estimating the residential dust hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative. This was reviewed by the SAB in July 2010
- Refining the approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.
- Developing an approach for estimating the dust hazard standards for interior renovations in P&CBs that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.
- Refining the approach for estimating hazard standards in residences and P&CBs after a second review by the SAB in December 2010.
- Development of an Approach to estimate benefits from exterior renovations of P&CBs that contain lead paint. Blood lead estimates were estimated using the IEUBK model and IQ changes were estimated for young children. This Approach document was completed in 2012 but was not released because of a settlement agreement which combined exterior and interior renovations for P&CBs.
- Development of an Approach to estimate benefits from exterior and interior renovations of P&CBs that contain lead based paint. Blood and bone lead estimates were estimated using an updated version of the Leggett model and IQ changes were estimated for children 0-10 while cardiovascular disease mortality,

reduced kidney function, and low birth weight health outcomes were estimated for adults. This Approach document was completed and released on August 6, 2014.

- The Approach document was then peer reviewed and a peer review report was received on February 27, 2015.

The Approach and its supporting documents was peer reviewed by a panel in January 2015. This work assignment will consist of a series of technical directions designed to refine the Approach to address peer review comments and to incorporate new data sources as they become available from a survey which will collect information on renovation activities in P&CBs.

### **III. STATEMENT OF WORK**

#### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

#### **Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. This work assignment will require contractor staff to be thoroughly familiar with the IQ change analysis that was performed for the 2008 LRRP final rule. That rule and directions to its support materials may be found at <http://www.epa.gov/lead/pubs/renovation.htm>. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this work assignment.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/O 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)*"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "*Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this work assignment until the quality assurance statement is reviewed and approved by the WAM and the OPPT QA Manager.

#### **Task 3: Update Leggett Model**

The contractor shall document all feedback and provide response to comments received from its External Peer Review of EPA's Approach, which included a question specific to the Leggett model. The contractor shall compare and contrast code between the ASCL version of Leggett in the All Ages Lead Model and the Fortran version of Leggett V5 using the program "kdiff" to show exact changes in the code and input file for this and subsequent tasks. The contractor shall document model input parameters, and data sources that are used by both versions of the Leggett model, and identify opportunities to make these parameters identical and/or identify



reasons why the parameters may be different between the two models. The contractor shall update the input file values for different parameters to match. Ensure that ACSL and Fortran versions give model outputs that are the same and/or +/-5% when the same set of model inputs is used.

#### **Task 4: Update Approach document and Appendices based on new Table of Contents**

The contractor shall complete updates to the Approach document to be called: Approach taken to Estimate Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings. The document and its supplementary files shall document changes from the August 2014 Approach and provide response to peer review. Delivery of the Approach Document and its supplemental files is expected to be iterative with drafts submitted starting in December 2015 and continuing through Summer 2016. The final report will have 10 chapters within the Approach document alongside six supplemental files. The contractor shall document versions carefully, incorporate comments from EPA, to determine when a chapter and/or supplemental file moves from draft to final status.

#### **Task 5: Finalize model inputs**

The contractor shall finalize the following model inputs based on interpretation of existing data or retrieval of new data through literature search of information request. The contractor shall finalize, with coordination from EPA, expected control options as they differ from baseline conditions. The contractor shall finalize the approach to match time spent in various public and commercial building with ingestion rates. The contractor shall. Most model inputs were finalized in work assignments 0-10 and 1-10.

#### **Task 6: Complete Model Code and Deterministic and Sensitivity Analysis Model Runs**

The contractor shall update, maintain, and finalize the model code to ensure that model inputs and outputs can be run efficiently. The contractor shall incorporate rolling averages, differences between baseline and control options, and differences in age groups based on work completed in Tasks 2 and 3. Under a previous work assignment, the contractor developed a data processing plan. The contractor shall work with EPA to scope any modelling updates and subsequent modeling outputs to ensure that this large amount of data can be processed and delivered to EPA within a period of no more than 3 weeks.

#### **Task 7: Refine model inputs based on Survey Feedback and Update Monte Carlo Probabilistic Modeling**

In summer 2016, EPA expects results from an industry survey to become available. By this point, the contractor shall have delivered all written report with the exception of written summaries of results and graphics which shall be filled in within 2 weeks of completion of model results. The last step in the analysis will be to update model inputs as needed based on survey feedback, refine scenarios, and run the Monte Carlo model.

### **IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [\*.d), \*.out, \*.opt, \*.ssn]).

## **V. DELIVERABLES AND SCHEDULE**

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3: Leggett Model	December 2015
Task 4: Update Report	Rolling December 2015 to July 2016
Task 5: Model inputs	December 2015
Task 6: Model code, Deterministic, and Sensitivity Analysis	December 2015 to February 2016
Model 7: Monte Carlo Model Results and Updated Report	August 2016

Note: All days are calendar days.

## **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

## **IX. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

### **Work Assignment Manager (WAM):**

Charles Bevington  
OPPT-RAD AB2  
[Bevington.charles@epa.gov](mailto:Bevington.charles@epa.gov)  
202-564-8814

### **Alternate Work Assignment Manager (Alt WAM):**

Laurence Libelo  
OPPT-RAD AB2  
[Libelo.laurence@epa.gov](mailto:Libelo.laurence@epa.gov)  
202-564-8553

## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

## DATA CHECKLIST FOR EVALUATING A STUDY

- 1.) Bibliographic identification of the study.

Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

- 2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
- 3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
- 4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
- 5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
- 6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 2-10	
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:	
Contract Number EP-C-14-001		Contract Period 11/01/2013 To 10/31/2016 Base <input checked="" type="checkbox"/> Option Period Number	
Contractor ICF INCORPORATED, L.L.C.		Title of Work Assignment/SF Site Name (P&CBs) for Pb Rulemaking	
Specify Section and paragraph of Contract SOW See Comments			
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval		Period of Performance From 11/01/2015 To 10/31/2016	
Comments: D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search			
<input type="checkbox"/> Superfund		Accounting and Appropriations Data	
		<input checked="" type="checkbox"/> Non-Superfund	
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.			
SFO (Max 2) <input type="checkbox"/>			
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)
		Budget Org/Code (Max 7)	Program Element (Max 9)
		Object Class (Max 4)	Amount (Dollars)
			(Cents)
			Site/Project (Max 8)
			Cost Org/Code (Max 7)
1			
2			
3			
4			
5			
Authorized Work Assignment Ceiling			
Contract Period: 11/01/2013 To 10/31/2016		Cost/Fee: \$0.00    LOE: 0	
This Action:		\$205,759.00    1,829	
Total:		\$205,759.00    1,829	
Work Plan / Cost Estimate Approvals			
Contractor WP Dated: 11/19/2015		Cost/Fee: \$205,759.00    LOE: 1,829	
Cumulative Approved:		Cost/Fee: \$205,759.00    LOE: 1,829	
Work Assignment Manager Name Charles Bevington		Branch/Mail Code:	
(Signature) _____ (Date) _____		Phone Number 202-564-8814	
		FAX Number:	
Project Officer Name Melissa Revely-Wilson		Branch/Mail Code:	
(Signature) _____ (Date) _____		Phone Number: 919-541-0207	
		FAX Number:	
Other Agency Official Name		Branch/Mail Code:	
(Signature) _____ (Date) _____		Phone Number:	
		FAX Number:	
Contracting Official Name		Branch/Mail Code:	
(Signature) <u>William Yade</u> (Date) <u>Dec 24/15</u>		Phone Number: 513-487-2852	
		FAX Number: 513-487-2107	